Avitia

For research use only (RUO)

Avitia Assays

Actionable, robust and cost-effective cancer hotspot panels

Introducing: Avitia Tissue and Plasma Assays

Find It®

(FFPE Tumor Tissue)

High performance amplicon panel assay designed for next-generation sequencing (NGS) to detect clinically actionable genomic mutations in solid tumor biopsies

Follow It®

(Liquid Biopsy)

Cost-effective amplicon panel assay designed for next-generation sequencing (NGS) to detect clinically actionable genomic mutations in cell-free circulating tumor DNA

Find It and Follow It Assays:

- Detect common, clinically actionable genomic alterations from solid tumor cancers including single nucleotide variants (SNVs), insertions and deletions (indels), 9 copy number variation (CNV) targets, and microsatellite instability (MSI)
- Evaluates somatic alterations of tumor DNA at >337 hotspots and 26 exons in 38 cancer associated genes simultaneously using next generation sequencing technology

Find It and Follow It target genomic mutations associated with solid tumors

Detect mutations known to have prognostic and diagnostic value to help inform treatment or predict disease progression

Identify potential therapeutics or eligibility for clinical trials

Find acquired resistance mutations to drugs and assists selection of alternative therapies

Detect MSI status as a potential indicator of eligibility for response to immunotherapy

Considerations

- The assays may not detect genetic alterations outside the defined set of genes. It may also not detect mutations below the test's detection limit.
- Follow It assay detects mutations in metastatic cancer cases only.

Focused on Actionable Results

38 cancer-associated genes, 26 exons, and >337 hotspots

- Find It and Follow It focus on carefully selected genes and hotspots where alterations can indicate sensitivity and resistance to approved and investigational therapeutics, diagnostic and prognostic cancer biomarkers.
- The assays provide a cost-effective solution via a small, focused, and robust panel.

Gene Content

SNVs & Indels (37 genes)						CNVs* (9 genes)		MSI*
AKT1	ALK	AR	BRAF	CTNNB1	DICER1	CCNE1	EGFR	21 Loci
DDR2	EGFR	ERBB2	ESR1	FGFR1	FGFR2	ERBB2	FGFR1	
FGFR3	FOXL2	GNA11	GNAQ	GNAS	HRAS	FGFR2	KIT	
IDH1	IDH2	KIT	KRAS	MAP2k1	MAP2K2	KRAS	MET	
MET	NRAS	NTRK1	NTRK3	PDGFRA	PIK3CA	PIK3CA		
POLE	PTCH1	PTEN	RET	ROS1	STK11			
TP53*								

CNVs*: Detecting amplifications only | TP53*: Full gene (all exons) covered

Fast and flexible with optimized performance

Both assays are validated on Illumina MiSeq and NextSeq, offering greater flexibility with higher throughput.

In addition to more flexibility in instrument choice, these new versions of Find It and Follow It offer easy wet lab workflows, fast analysis runs, and greater sensitivity than ever before.

The most common solid tumor cancer types are associated with both Find It and Follow It gene content

Cancer	Associated Genes	Relevant assay
Basal Cell Carcinoma	*PTCH1, TP53*	Find It
Breast Cancer	*AKT1, BRAF, ERBB2* (HER2), *ESR1, FGFR1, FGFR2, KIT, PIK3CA, PTEN, TP53, MSI*	Find It and Follow It (metastatic)
Colorectal Cancer	*AKT1, BRAF, CTNNB1, EGFR, ERBB2* (HER2), *FGFR1, FGFR2, GNAS, KRAS, MET, MAP2K1, NRAS, PIK3CA, PTEN, POLE, TP53, MSI*	Find It and Follow It (metastatic)
Cholangiocarcinoma	*BRAF, IDH1*	Find It and Follow It (metastatic)
Endometrial Cancer	*AKT1, CCNE1, CTNNB1, FGFR2, KRAS, PIK3CA, PTEN, POLE, TP53, MSI*	Find It and Follow it (metastatic)
Esophageal	*ERBB2* (HER2)	Find It
Gastric	*ERBB2* (HER2), *FGFR2, KRAS, PIK3CA, PTEN, TP53, MSI*	Find It and Follow It (metastatic)
GIST	*BRAF, KIT, PDGFRA, TP53*	Find It
Glioma	*BRAF, EGFR, ERBB2* (HER2), *FGFR1, IDH1, IDH2, KIT, PIK3CA, PTEN, TP53*	Find It
Head and Neck Cancer	*BRAF, DDR2, MET, PIK3CA, TP53*	Find It and Follow It (metastatic)
Lung Cancer	*ALK, BRAF, DDR2, EGFR, ERBB2* (HER2), *FGFR1, FGFR2, KRAS, MAP2K1, MET, NRAS, NTRK1, NTRK3, PIK3CA, PTEN, ROS1, STK11, TP53, MSI*	Find It and Follow It (metastatic)
Melanoma	*BRAF, CTNNB1, GNA11, GNAQ, KIT, MAP2K1, NRAS, STK11, TP53*	Find It and Follow It (metastatic)
Neuroblastoma	*ALK, FGFR3, HRAS, PIK3CA, TP53*	Find It
Ovarian Cancer	*AKT1, BRAF, CCNE1, CTNNB1, DICER1, ERBB2* (HER2), *FGFR1, FOXL2, KRAS, MAP2K1, NRAS, PIK3CA, PTEN, TP53*	Find It and Follow It (metastatic)
Pancreatic Cancer	*CTNNB1, KRAS, MAP2K2, STK11, TP53*	Find It and Follow It (metastatic)
Prostate Cancer	*AR, KRAS, PTEN, TP53*	Find It
Thymic Cancer	*KIT, TP53*	Find It
Thyroid Cancer	*BRAF, CTNNB1, HRAS, KRAS, NRAS, PIK3CA, RET, TP53*	Find It and Follow It (metastatic)
Urothelial Cancer	*FGFR3, HRAS, PIK3CA, TP53*	Find It and Follow It (metastatic)

Find It and Follow It are focused on gene mutations that can be addressed through current FDA approved therapies

Indication	Biomarker		FDA Approved Drugs*
All Solid Tumors	Microsatellite instability-high (MSI-H)	→	Pembrolizumab
	NTRK1 and NTRK3 mutations	→	Resistance to Larotrectinib
	NTRK1 G595R	→	Resistance to Entrectinib
Anaplastic Thyroid Cancer	BRAF V600 or V600E	→	Dabrafenib + Trametinib
Basal Cell	PTCH1 oncogenic mutations	→	Vismodegib, Sonidegib
Breast Cancer	ERBB2 amplification	→	Ado-Trastuzumab Emtansine | Lapatinib + Capecitabine, Lapatinib + Letrozole | Margetuximab + Chemotherapy | Neratinib + Capecitabine, Neratinib | Trastuzumab + Pertuzumab + Chemotherapy | Trastuzumab + Tucatinib + Capecitabine | Trastuzumab deruxtecan | Trastuzumab, Trastuzumab + Chemotherapy
	PIK3CA oncogenic mutations	→	Fulvestrant + Alpelisib
	MSI-H	→	Pembrolizumab
Colorectal Cancer	BRAF V600E	→	Encorafenib + Cetuximab | Panitumumab
	ERBB2 Amplification	→	Lapatinib + Trastuzumab | Trastuzumab + Pertuzumab | Trastuzumab deruxtecan | Resistance to Cetuximab
	KRAS wild type	→	Cetuximab, Regorafenib
	KRAS and NRAS wild-type	→	Panitumumab
	KRAS and NRAS oncogenic mutations	→	Resitance to Panitumumab, Cetuximab
	MSI	→	Pembrolizumab, Nivolumab, Ipilimumab + Nivolumab
Endometrial	MSI/ MMRd	→	Dostarlimab-gxly
Esophageal	ERBB2 Amplification	→	Trastuzumab + Chemotherapy, Trastuzumab deruxtecan
Gastric Cancer	ERBB2 amplification	→	Pembrolizumab + Trastuzumab + Chemotherapy
	MSI	→	Pembrolizumab
GIST	KIT oncogenic mutations	→	Imatinib | Sunitinib | Regorafenib | Ripretinib
	KIT A829, D816, D820, N822, T670, V654, Y823	→	Resistance to Imatinib, Sunitinib
	PDGFRA oncogenic mutations	→	Imatinib | Regorafenib | Ripretinib | Sunitinib
	PDGFRA D842	→	Resistance to Imatinib
	PDGFRA exon 18 mutations	→	FDA approval: Avapritinib
Medullary Thyroid Cancer	RET oncogenic mutations	→	Pralsetinib, Selpercatinib
Melanoma	BRAF V600	→	Vemurafenib + Atezolizumab + Cobimetinib, Dabrafenib + Trametinib, Encorafenib + Binimetinib, Vemurafenib + Cobimetinib
	BRAF V600E	→	dabrafenib or vemurafenib
	BRAF V600E or V600K	→	Trametinib | Dabrafenib + Trametinib, Encorafenib + Binimetinib, Vemurafenib + Cobimetinib
	KIT oncogenic mutations	→	Imatinib
NSCLC	ALK oncogenic mutations	→	Brigatinib, Lorlatinib | Resistance to Alectinib, Crizotinib
	BRAF V600E	→	Dabrafenib + Trametinib
	EGFR G719 (exon 18), exon 19 deletions, S768I (exon 20), L858R, L861Q (exon21)	→	Afatinib
	EGFR exon 19 deletions, L858R (exon 21)	→	Osimertinib, Gefitinib, Erlotinib, Dacomitinib, Erlotinib + Ramucirumab
	EGFR exon 20 insertion, T790M (exon 20)	→	Resistance to Afatinib, Erlotinib, Gefitinib
	EGFR T790M (exon 20), L858R (exon 21)	→	Osimertinib
	EGFR C797, L718, L792, G796	→	Resistance to Osimertinib
	EGFR exon 20 insertion	→	Erlotinib, Amivantamab-vmjw
	ERBB2 oncogenic mutations	→	Ado-Trastuzumab Emtansine | Trastuzumab Deruxtecan
	MET exon 14 skipping	→	Capmatinib, Tepotinib, Crizotinib
	MET amplification	→	Crizotinib
	MET amplification	→	Resistance to Erlotinib, Osimertinib, Gefitinib
	KRAS G12C	→	FDA approval: Sotorasib
Urothelial	FGFR3 R248C, S249C, G370C, Y373C	→	Erdafitinib

From sample to clinical report in 5 business days

- Sample preparation, laboratory assay workflow, NGS sequencing and clinical reporting are all completed within your own laboratory.
- The Avitia bioinformatics pipelines will be run automatically in the cloud with results populating into a secure web accessible clinical reporting portal.
- Our clinical reporting portal helps your experts identify actionable mutations, link to interpretations and clinical trials for output into a simple report.

Day 1 — Day 5

Local Laboratory

Sample

Find It: Histological assessment and preparation of FFPE tumor slides or scrolls/curls

Follow It: Collection of peripheral whole blood in DNA stabilization tubes

DNA Extraction

Find It: DNA extracted from formalin-fixed paraffin embedded (FFPE) solid tumor cancers

Follow It: Plasma cell-free circulating DNA (cfDNA)

Multiplex PCR

Multiplex PCR to amplify targets

Library Preparation & Sequencing

Construct library, prepare template, and run NGS

Cloud Based Services

Bioinformatics

Automated machine learning pipeline performs data analysis and variant calling

Expert Interpretations/ Clinical Trials Database

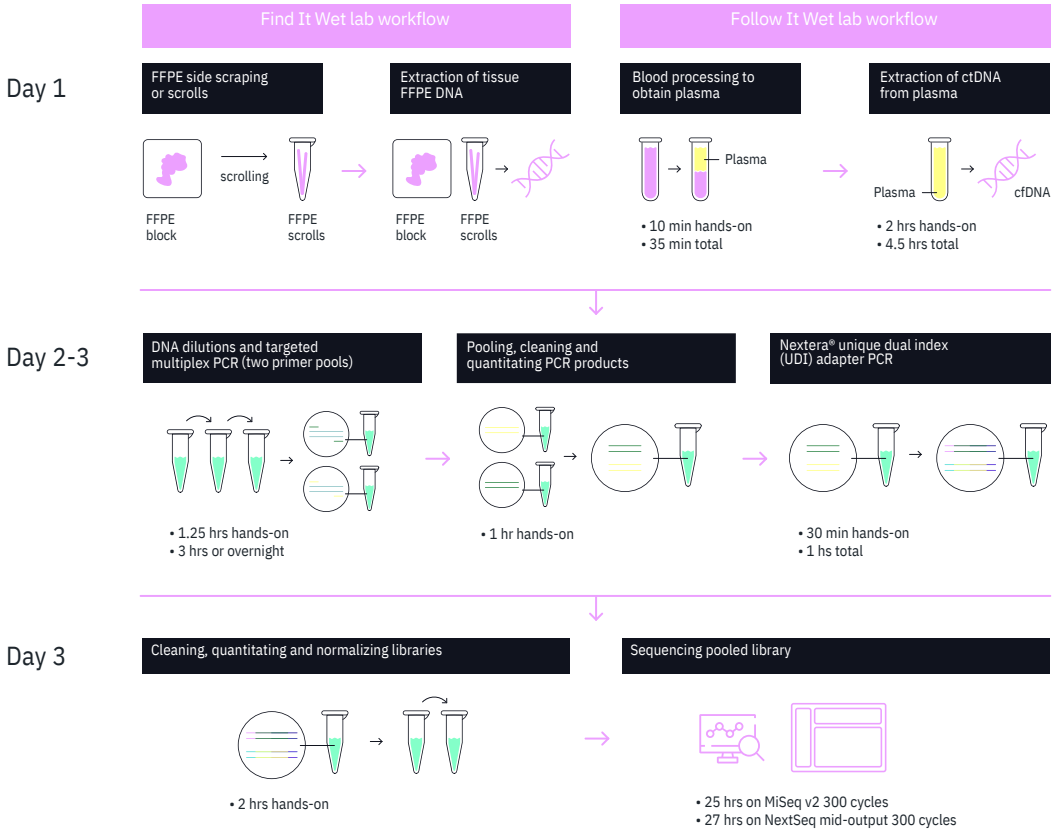
Experts review mutation results & match them with approved drugs. They will also identify any available relevant clinical trials adapted for health jurisdiction

Local Computer

Report

Report is issued & delivered to the healthcare professional on the 5th day. The report is accompanied by a short patient report

Get faster results with Find It and Follow It streamlined laboratory workflow



Accurate and Robust Genome Analytics

A precision oncology platform powered by artificial intelligence.

- Avitia assays are supported by a robust, accurate, and high-throughput bioinformatics system, the Avitia Insights Platform, for accurate identification of mutations.
- The central component of this system is a proprietary bioinformatics and genome analytics pipeline. The pipeline has been built on proprietary machine learning computational algorithms and has been rigorously validated.

Timely and Secure Results

Results can be delivered quickly to your research or health providers through our secure, automated, and integrated system. With the ability to integrate easily with your internal LIMS or EMR systems, manual data entry is reduced and PHI data remains secure.

Comprehensive and Informative Reports

All the information needed in a simplified, straightforward format

Reports automatically generated from the Avitia Insights Platform provide a summary of the mutation results and present interpretations and therapeutic recommendations. Additionally, available clinical trials can be chosen based on the gene mutations identified by the assay.

- Clinical trials are carefully curated by a certified clinical molecular geneticist using specific trial eligibility criteria including tumor molecular profile, organ, and histological type.
- Clinical profiles are automatically matched to trials based on the presence or absence of gene mutations, tumor type, histological type, and availability of the trial in the country of the laboratory's jurisdiction.
- The system provides full flexibility to modify and refine precompiled report recommendations, and, if necessary, create new interpretations and recommendations on the fly.
- The reporting information within the Avitia Insights Platform is updated regularly to include recently added trials and the status of existing clinical trials.

Summary of Results

A summary of the results indicating whether mutations are present or absent, therapeutic implication, number of clinical trials available

Therapeutic Implications

Therapeutic recommendations based on the gene mutation and the clinical data

Clinical Trials

Matches open and curated clinical trials to a tumor specific genomic profile based on the presence or absence of gene mutations, tumor type, histological type, and availability of the trial in the country of the laboratory's jurisdiction

Quality Control and Assurance

Avitia ensures accuracy and quality control through a set of quality assurance methods utilizing DNA sequence barcodes known as Quality Nexus®. Quality Nexus is incorporated into the assay and bioinformatics pipeline.

Quality Nexus

- Improves the signal to noise ratio enabling detection of mutations at significantly lower variant allele frequency (VAF)
- Enables robust mutation detection across full range of clinical diagnostic samples collected in routine pathology workflows

Benefits to your lab

01 Key Content

Target genomic content associated with approved therapies, treatment resistance, disease prognosis, and clinical trials

02 Fast Turnaround Time

A simple laboratory workflow that provides rapid, reliable results in as little as 5 days

03 Comprehensive Report

Automated reporting from the Avitia Insights Platform provides up-to-date information on interpretations, current treatment options, and available clinical trials

04 Cost-Effective

Targeted amplicon-based technology provides an economical alternative to single-gene testing or hybrid capture NGS assay

Our Story

Avitia makes high-quality genomic information accessible and affordable to support cancer treatment selection and monitoring. Our oncology software platform and clinical services enable actionable, cost-effective, and fast interpretation for next-generation sequencing assays. Together with healthcare and diagnostic partners, we are leading the shift towards precision oncology.

Technical Specifications	
Genes	38
Hotspots	>337
Exons	26
Turnaround Time	5 days
Mutation Types	SNVs, deletions and insertions 9 CNV targets, and microsatellite instability
Find It Sample Type and Requirement	FFPE blocks, scrolls, cores & unstained slides FFPE blocks or unstained slides (5-10um sections) with a minimum of 10% tumor cellularity. Scrolls, cores or DNA must be submitted with representative H&E
Follow It Sample Type and Requirement	Whole peripheral blood collected in stabilization tubes 2 X 10mL of blood in Streck tubes

Follow It performance

Mutation Type	LOD90	Sensitivity	Specificity	Negative Predictive Value
SNVs	≥0.375%	90%	>99%	>0.999
Indels	≥0.375%	90%	>96%	1.000
CNVs	≥2.4	100%	>92%	1.000

Find It performance

Mutation Type	LOD95	Sensitivity	Specificity	Negative Predictive Value
SNVs	≥1%	100%	100%	1.000
Indels	≥1%	100%	100%	1.000
CNVs	≥2.8	100%	>82%*	1.000

Removing; CCNE1, CNVs specificity is >=96%

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Product Disclaimer: Find It & Follow it was developed in a CAP,CLIA, DAP, and CDPH accredited/licensed laboratory. Find It & Follow It are intended for research use only (RUO) and are not intended for the diagnosis, prevention or treatment of a disease.